

# Notice of Allowability

Application No.

09/856,694

Examiner

Ruth A. Davis

Applicant(s)

SIMON ET AL.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Remand on 7/27/2006.
2. ☒ The allowed claim(s) is/are 36-45 and 56-67.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20061027.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patricia Granados on October 27, 2006.

The application has been amended as follows:

In the claims:

Claims 1-35 (canceled).

36. (Currently Amended) A method for treating a skin condition, comprising administering to a subject in need thereof an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) active agent consisting of ~~(i) hyperforin or (ii)~~ hyperforin and hypericin, ~~wherein said condition is selected from the group consisting of an inflammatory skin condition, a precancerous condition, a geriatric skin condition, and a microbial skin infection.~~

37. (Currently Amended) The method according to claim 36, wherein the skin condition is eczema.

38. (Currently Amended) The method according to claim 36, wherein said condition is selected from the group consisting of exsiccation eczemas, hyperkeratotic hand and foot eczemas, contact eczemas, atopic dermatitis, neurodermatitis, lichen simplex, **and** prurigo simplex, ~~lymphomas, leukemia, melanoma, an epithelial pre-cancerous condition, tumor metastases, and epithelial tumor.~~

39. The method according to claim 36, wherein said subject is a mammal.

40. The method according to claim 36, wherein said composition is in the form of a topical ointment and said effective amount consists of at least 15  $\mu\text{g}$  hyperforin per ml of the composition.

41. The method according to claim 36, wherein said composition is in the form of a topical ointment and said effective amount is 0.02-20 mg hyperforin per ml of the composition.

42. The method according to claim 41 wherein said effective amount is 1-20 mg hyperforin per ml of the composition.

43. The method according to claim 42 wherein said effective amount is 10 mg hyperforin per ml of the composition.

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44. The method according to claim 36, wherein said effective amount is at least 15  $\mu$ g hypericin per ml of the composition.

45. The method according to claim 36, wherein said effective amount of hypericin is 20-150  $\mu$ g hypericin per ml of the composition.

Claims 46-55 (Cancelled)

56. (Currently Amended) The method of claim ~~46~~ 36, wherein said hyperforin is at least 90% pure.

57. (NEW) A method for treating a tumor, comprising administering to a subject in need thereof an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) active agent consisting of (i) hyperforin or (ii) hyperforin and hypericin.

58. (NEW) The method according to claim 57, wherein said tumor is selected from the group consisting of a lymphoma, leukemia, melanoma, an epithelial tumor, and a metastatic tumor.

59. (NEW) The method according to claim 57, wherein said subject is a mammal.

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60. (NEW) The method according to claim 57, wherein said composition is in the form of a topical ointment and said effective amount consists of at least 15  $\mu\text{g}$  hyperforin per ml of the composition.
61. (NEW) The method according to claim 57, wherein said composition is in the form of a topical ointment and said effective amount is 0.02-20 mg hyperforin per ml of the composition.
62. (NEW) The method according to claim 61 wherein said effective amount is 1-20 mg hyperforin per ml of the composition.
63. (NEW) The method according to claim 62 wherein said effective amount is 10 mg hyperforin per ml of the composition.
64. (NEW) The method according to claim 57, wherein said effective amount is at least 15  $\mu\text{g}$  hypericin per ml of the composition.
65. (NEW) The method according to claim 57, wherein said effective amount of hypericin is 20-150  $\mu\text{g}$  hypericin per ml of the composition.
66. (NEW) The method of claim 57, wherein said hyperforin is at least 90% pure.

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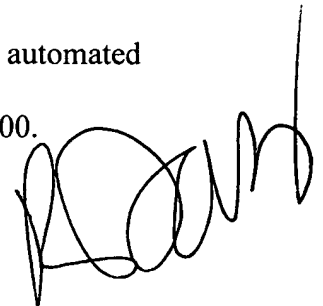
67. (NEW) The method of claim 36, wherein said skin condition is selected from the group consisting of inflammatory skin condition, a precancerous skin condition, a geriatric skin condition, and a microbial skin infection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth A. Davis  
Primary Examiner  
Art Unit 1651



October 27, 2006